Applicants have canceled all composition claims and now only pursue process claims for producing a dosage form. Applicants reserve the right to pursue canceled subject matter in a subsequent continuation application.

Applicants have also added claims 68-86, which correlate to original dependent claims 19-37. Previously considered claims 19-37 have been rewritten as claims 68-86 to change their dependency from the canceled composition claims to the still pending process claims. Applicants have further added new claim 87. Support for new claim 87 can be found in page 17, first paragraph, of the original specification as filed.

Applicants respectfully submit that the claim amendments submitted herewith do not add any new matter within the meaning of 35 U.S.C. §132 to the application.

Accordingly, entry of the above amendments is respectfully requested.

Interview Summary

Applicants take this opportunity to thank Examiner Silverman for the telephonic interview conducted on August 13, 2007. During the interview, applicants' representative discussed the possibility of pursuing only process claims in the current application, canceling composition claims 18-37 and process claims 53-55, and pursuing the canceled subject matter in one or more continuation applications. The Examiner indicated there should be no problem pursuing canceled subject matter in a continuation application, as long as Applicants identified any relevant prior prosecution history.

The remaining process claims were discussed and their patentability over the disclosure contained in the cited Ghebre-Selassie et al. document. Applicants pointed out

that the current process claims recite the use of "aqueous PVP" while the Ghebre-Selassie method teaches use of only "solvent-free" PVP in the core of the granules. The Ghebre-Selassie method does not suggest a granulation step from aqueous solutions comprising PVP. Instead, Ghebre-Selassie clearly teaches adding PVP to a plasticizer/solubilizer as a prerequisite in the described processes.

1. Rejection of Claims 18-23 and 25-67 under 35 U.S.C. §103(a)

The Official Action states that claims 18-23, 25-32, 36, 37, and 58-67 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Rennard, et al. (US Published Application No. 20030018071) in combination with Ghebre-Sellassie et al. (US Patent No. 6,667,362) and Thakkar (U.S. Patent No. 4,024,240) for reasons of record. Further, the Official Action states that claims 33-35 and 38-57 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Rennard, et al. (US Published Application No. 20030018071) in combination with Ghebre-Sellassie et al. (US Patent No. 6,667,362) and Thakkar (U.S. Patent No. 4,024,240) and further in view of Remington: The Science and Practice of Pharmacy, 1995.

RESPONSE

Applicants respectfully traverse this rejection. The above amendment canceling claims 18-23, 25-37, 49-52, 56-64, and 66-67 renders this rejection moot for these claims. Claims 38-48, 53-55, 65, and new claims 68-87 remain pending. The cited references do not teach or suggest applicants' subject matter as a whole as recited in these claims. The

Examiner has failed to establish a *prima facie* case of obviousness against the presently rejected claims.

To establish a *prima facie* case of obviousness, the PTO must satisfy three requirements. First, as the U.S. Supreme Court very recently held in *KSR International Co. v. Teleflex Inc. et al.*, Slip Opinion No. 04–1350, 550 U. S. ____ (April 30, 2007), "a court must ask whether the improvement is more than the predictable use of prior art elements according to their established functions. ...it [may] be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue. ...it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does... because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known." (*KSR*, *supra*, slip opinion at 13-15.) Second, the proposed modification of the prior art must have had a reasonable expectation of success, determined from the vantage point of the skilled artisan at the time the invention was made. *Amgen Inc. v. Chugai Pharm. Co.*, 18 USPQ2d 1016, 1023 (Fed. Cir. 1991). Lastly, the prior art references must teach or suggest all the limitations of the claims. *In re Wilson*, 165 USPQ 494, 496 (C.C.P.A. 1970).

A *prima facie* case of obviousness must also include a showing of the reasons why it

would have been obvious to modify the references to produce the presently pending claims. See *Ex parte Clapp*, 277 USPQ 972, 973 (Bd. Pat. App. & Inter. 1985). The Examiner bears the initial burden to provide some convincing line of reasoning as to why the ordinary skilled artisan would have found the claimed invention to have been obvious in light of the reference teachings. *Id.* at 974.

Further, applicant notes that a *prima facie* case of obviousness can be rebutted if she can show "that the art in any material respect taught away" from the claimed invention. *In re Geisler*, 43 USPQ2d 1362, 1365 (Fed. Cir. 1997).

Applicants have canceled all composition claims, and only claims directed to a process for producing a dosage form remain under examination.

As has been discussed with the Examiner in the telephonic interview of August 13, 2007, the current process claims are not rendered obvious by the combination of cited references because they do not teach or suggest all of the claim limitations.

The primary Rennard et al. reference teaches the combination of certain PDE4 inhibitors with a pharmaceutical carrier. The Rennard reference does not teach each and every element of the presently pending claims. In particular, it does not teach a process for producing a dosage form using PVP in any amount.

The secondary Ghebre-Sellassie, et al. reference teaches a method for preparing a drug-PVP dosage form using only "solvent-free" PVP. See Example I, and claim 1. The Ghebre-Selassie method teaches spraying the required plasticizer/solubilizer on a solvent-free complex of PVP and active drug to form granules having a drug-PVP core coated with plasticizer/solubilizer. See Example I, and claim 1. Accordingly, Ghebre-Selassie does not

teach the use of "aqueous PVP" as required by the presently pending claims. Further, the Ghebre-Selassie method teaches use of only "solvent-free" PVP in the core of the granules. The Ghebre-Selassie method does not suggest a granulation step from aqueous solutions comprising PVP, as required by the presently pending claims. Instead, Ghebre-Selassie clearly teaches adding PVP to a plasticizer/solubilizer as a prerequisite in the described processes.

The Thakkar reference teaches antibiotic compositions which contain PVP in the form of a dispersion. The Thakkar reference does not teach spraying PVP to form the outside of a granule containing an active drug with low solubility.

The Remington reference discusses the use of PVP as a binder for preparation of dosage forms by using either aqueous or alcoholic solutions. Page 1618, bottom of column 1. However, the Remington reference does not suggest a granulation step from aqueous solutions comprising PVP, as required by the presently pending claims.

As noted above, applicants respectfully point out that the current process claims recite the use of "aqueous PVP" while the Ghebre-Selassie method teaches use of only "solvent-free" PVP in the core of the granules. The Ghebre-Selassie method does not suggest a granulation step from aqueous solutions comprising PVP. Instead, Ghebre-Selassie clearly teaches adding PVP to a plasticizer/solubilizer as a prerequisite in the described processes. Neither does the combination of references correct these deficiencies, and fails to teach a process for producing a dosage form by granulation of an active drug complex with an aqueous PVP.

Accordingly, the combination of art cited by the Examiner, taken alone or in

combination, does not teach or suggest each and every element of the presently pending claims.

Therefore, the Examiner is respectfully requested to reconsider and withdraw this rejection under 35 USC §103(a) and allow currently pending claims 38-48, 53-55, 65, and 68-87.

CONCLUSION

In view of the above amendments and remarks, Applicants submit that this application is in condition for allowance. Accordingly, Applicants respectfully request entry of the amendment, reconsideration and withdrawal of the rejections, and allowance of the claims. An early and favorable action is earnestly solicited.

If the Examiner has any questions or wishes to discuss this matter, the Examiner is welcomed to telephone the undersigned attorney.

Respectfully submitted,

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